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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,263	06/23/2006	Barry Dean Briggs	38187-2804.US	3301
77845 Goodwin Proc	7590 10/28/201 ster LLP	EXAMINER		
Attn: Patent Administrator			EISEMAN, ADAM JARED	
135 Commony Menlo Park, C	wealth Drive A 94025-1105	ART UNIT	PAPER NUMBER	
,			3736	
			NOTIFICATION DATE	DELIVERY MODE
			10/28/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patentsv@goodwinprocter.com dnakley@goodwinprocter.com

# Office Action Summary

Annlinetian Na	A	
Application No.	Applicant(s)	
10/560,263	BRIGGS ET AL.	
Examiner	Art Unit	
ADAM J. EISEMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

earned	patent term adjus	stment. See 37 CF	R 1.704(b).

WHICHEVER I  - Extensions of time after SIX (6) MON  - If NO period for re - Failure to reply wit Any reply received	D STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, IS LONGER, FROM THE MALLING DATE OF THIS COMMUNICATION.  Imay be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed THS from the mailing date of this communication.  The specific provides of the communication of the c			
Status				
1) Respons	ive to communication(s) filed on 09 August 2010.			
2a) This action	on is FINAL. 2b) This action is non-final.			
3)☐ Since thi	s application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in	accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Cla	aims			
4) Claim(s)	7-13.32,34-37 and 41 is/are pending in the application.			
4a) Of the	4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s)	Claim(s) is/are allowed.			
6)⊠ Claim(s)	☑ Claim(s) <u>7-13.32,34-37 and 41</u> is/are rejected.			
7) Claim(s)	7) Claim(s) is/are objected to.			
8) Claim(s)	are subject to restriction and/or election requirement.			
Application Paper	rs			
9)☐ The spec	ification is objected to by the Examiner.			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
Applicant	may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacem	nent drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11)∐ The oath	or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35	U.S.C. § 119			
12) Acknowle	edgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a)∐ All b	) Some * c) None of:			
1.☐ Ce	ertified copies of the priority documents have been received.			
2.☐ Ce	ertified copies of the priority documents have been received in Application No			
3.☐ Co	ppies of the certified copies of the priority documents have been received in this National Stage			
ap	plication from the International Bureau (PCT Rule 17.2(a)).			
* See the at	tached detailed Office action for a list of the certified copies not received.			

Attachment(s) 1) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/06)

4) Interview Summary (PTO-413) Paper No(s)/Mail Date.\_\_\_.

8) Notice of Informal Patent Application.

6) Other: \_\_\_

Paper No(s)/Mail Date

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#### DETAILED ACTION

 This action is responsive to applicant's amendments and arguments/remarks filed on 8/9/2010.

#### Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/7/2010 was filed after the mailing date of the first office action on 6/8/2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

## Claim Rejections - 35 USC § 112

 The previously held 112 rejections are withdrawn in view of the applicants amendments and claim cancellations.

## Claim Rejections - 35 USC § 103

- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- Claims 7-12 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al (US 5,971,941) in view of Lum et al (US 2002/0042594).

Simons discloses a device for body fluid sampling usable with a cartridge housing a plurality of penetrating members (column 5, line 45 – column 9, line 61), the device comprising: a housing (figures 6 and 7); a penetrating driver couple to said housing and for use with said cartridge (column 9, line 63 – column 12, line 29); wherein the penetrating member driver moves at least on of said penetrating members at

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velocities with conform with a velocity profile (column 9, line 63 – column 12, line 29); and a processor.

However, Simons does not disclose the processor is used for controlling the penetrating member driver along the velocity profiles.

Lum teaches the use of a processor used to control a penetrating member driver in order to move it along a desired velocity profile (paragraph [0023]).

Regarding claims 7-12 and 32; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Simons cartridge based fluid sampling device use it's processor for controlling the penetrating member driver as taught by Lum in order to move the penetrating member along a desired path and velocity profile.

Further regarding claim 8; Simons discloses a cartridge housing a plurality of penetrating members and a window allowing a user to see the cartridge while the cartridge is in said housing (see figure 7).

Further regarding claims 9-11 and 32; Simons discloses the device has a display for displaying any information about the status of the measurement (column 13, lines 4-31). It would have been obvious to one of ordinary skill in the art at the time of the invention that device status, lancing performance and lancing parameters are all information regarding the status of the measurement and lancing performed by the Simons/Lum device. Furthermore, it was well known in the art at the time of the invention to use screen savers on LCD displays to show inactivity and increase the LCD display life.

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Further regarding claim 12; Simons discloses a single button for actuating the lancet along is path into and out of the tissue (column 13, line 57 – column 14, line 10).

#### Allowable Subject Matter

- Claims 34-37 are allowed.
- 7. The following is a statement of reasons for the indication of allowable subject matter: Claims 34-37 disclose a device novel over the prior art for sampling body fluid using a cartridge and meter having a mechanism for advancing the penetrating members of the cartridge into a firing position, removing a sterility barrier from the cartridge to expose the penetrating member and firing/retracting the penetrating members from the cartridge. The prior art of record does not disclose a mechanism having the claimed structure for advancing the cartridge and for moving a sterility barrier located on the cartridge.

### Response to Amendment

8. Applicant's arguments filed 8/9/2010 have been fully considered but they are not persuasive. The applicant argues that Lum fails to disclose a processor for controlling the velocity profile of the penetrating member. The examiner disagrees with the applicant's assessment of Lum and contends that Lum's disclosed processor is capable of controlling the penetrating member according to how much current is supplied to the driving device and is thus is inherently capable of controlling the velocity profile of the penetrating member.

#### Conclusion

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 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE 10/22/2010 /A. J. E./ Examiner, Art Unit 3736

/Max Hindenburg/ Supervisory Patent Examiner, Art Unit 3736